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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,265	01/26/2006	George A. Gaitanaris	700128.401USPC	2916

500 7590 08/09/2006

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
701 FIFTH AVE  
SUITE 6300  
SEATTLE, WA 98104-7092

EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,265	<b>Applicant(s)</b> GAITANARIS ET AL.	
	<b>Examiner</b> John D. Ulm	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 643-675 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 643-675 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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Claims 643 to 675 are pending in the instant application.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I to CLVIII, claims 643 to 645, only in so far as they are drawn to a substantially pure polypeptide comprising one of the 158 different amino acid sequences listed in Table 2 of the instant application, and an isolated polynucleotide encoding that sequence. Invention I, for example, includes claims 643 to 645 only in so far as they relate to SEQ ID NOs: 1 and 2 whereas invention CLVIII includes claims 643 to 645 only in so far as they relate to SEQ ID NOs: 252 and 253.

Groups ?, claims 646, 651, 661 and 662, only in so far as they are drawn to a method of diagnosis involving genetic analysis by identifying an alteration in **one** of the plurality of genes listed in Tables 3 to 14 and 33 of the instant specification. The exact number on inventions has not been determined because the number of different genes listed in the plurality of tables recited in these claims does not appear to be disclosed in the instant specification. However, a method of genetic analysis by detecting a polymorphism in the well known gene product CCR5, for example, does not reflect a common inventive concept with a method of genetic analysis by detecting a polymorphism in the well known gene product EDG1.

Groups ?, claims 647 to 650, 661 and 662, only in so far as they are drawn to a method of diagnosis involving measuring the level of expression or activity of **one** of the plurality of proteins listed in Tables 3 to 14 and 33 of the instant specification.

Groups ?, claims 652, 653, 661 and 662, only in so far as they are drawn to a method of treatment by administering a polynucleotide encoding **one** of the plurality of different proteins listed in Tables 3 to 14 and 33 of the instant specification.

Groups ?, claims 654, 661 and 662, only in so far as they are drawn to a method of treatment by administering a compound of unspecified constitution that modulates the biological activity of **one** of the plurality of proteins listed in Tables 3 to 14 and 33 of the instant specification.

Groups ?, claims 655 and 658 to 662, only in so far as they are drawn to a binding assay employing **one** of the plurality of receptor proteins listed in Tables 3 to 14 and 33 of the instant specification.

Groups ?, claims 656, 657, 661 and 662, only in so far as they are drawn to a method of identifying a compound that effects the level of expression of a gene encoding **one** of the plurality of proteins listed in Tables 3 to 14 and 33 of the instant specification.

Groups ?, claims 663 to 675, only in so far as they relate to a transgenic animal comprising a gene encoding **one** of the 776 different proteins listed in Table 1 of the instant specification, or a mutant thereof.

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The plurality of different inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The 776 different proteins listed in Table 1 of the instant specification lack unity of invention because they lack a common utility that is based upon a common feature or combination of features that distinguishes them as a group from the prior art. Whereas the plurality of different amino acid sequences listed in the various tables that are recited in the claims correspond to the amino acid sequences of mammalian G protein-coupled receptors, a substantial number of those sequences are the amino acid sequence of receptor proteins that are old and well known in the art, such as EDG1 and CCR5. Further, whereas the products claimed are isolated polypeptides, the claimed methods do not reflect a common inventive concept because they do not require those products in an isolated state, and the claimed animals do not express "isolated" proteins.

The diagnostic methods of claims 646 and 651 do not share a common inventive concept with the diagnostic methods of claims 647 to 650 because different parameters are being measured, different reagents are employed, and the methods have different modes of operation.

The methods of treating recited in claims 652 and 653 do not share a common inventive concept with the methods of treating recited in claims 654 and 661 because they have different modes of operation and employ chemically and structurally unrelated therapeutics.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

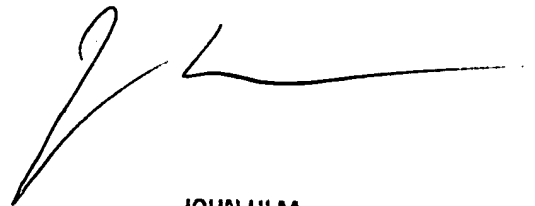
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800